GOVERNMENT APPROACHES TO THE MANAGEMENT OF MEDICAL TECHNOLOGY*

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THE postwar scientific explosion has had a major impact on the armamentarium available to physicians and patients, and today's hospital is a far cry from our medical institutions at the turn of the century. The development of sophisticated technology has also played an important role in the increase in specialization, both in professional manpower and in institutions. My specific focus today, however, is the relation of the federal government to the development and diffusion of and reimbursement for medical technology. I shall review the legislation and federal agencies that are involved in the management of medical technology and then comment upon some of the issues facing us.

But before pursuing this let me briefly describe the role of the Office of Technology Assessment. Established by law in 1974, and governed by a Congressional board of six representatives and six senators, equally divided by party, the office is charged to provide the Congress "early indications of the probable beneficial and adverse impacts of the applications of technology." In response to this charge, the Health Program of the Office of Technology Assessment has studied the development of medical technology, the assessment of its safety and efficacy, and is currently completing a study of the usefulness of cost effectiveness analysis in making decisions regarding resource allocations. I shall refer to several of these studies in the course of my discussion. For today's discussion, let me begin with the definition of medical technology used by our office, namely, the drugs, devices, and medical and surgical procedures used in medical care and the organization and supportive systems within which

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such care is provided. Thus, medical technology is clearly as old as medicine itself, but there is also no question that proliferation of types and increase in complexity of medical technology has occurred at a rapid rate. The period from 1940 to 1965 saw the introduction of a broad array of medical interventions, including new drugs and vaccines, cardiovascular surgery, renal dialysis, etc. Although several such dramatic advances as computerized tomography have been introduced since 1965, the major change during the last 15 years has been the diffusion and increased use of existing technologies rather than proliferation of new ones.

Government interest in management of technology dates back to 1902 and was virtually limited to issues of safety. The first act to regulate medical technologies was quite likely the 1902 Virus Serum and Toxins Act that established the federal government's authority to evaluate the safety of biological products intended for human use and to license acceptable products for marketing. The Pure Food and Drug Act of 1906 prohibited the manufacture, sale, and transportation of misbranded or adulterated food and drugs, and from that time until 1962 virtually all efforts of the Congress and the Food and Drug Administration (established in 1927) were directed toward assuring the public that the drugs they purchased were safe and properly labeled. The concern for efficacy was first clearly addressed in the 1962 amendments to the Food, Drug and Cosmetic Act, amendments that required the manufacturer to show "substantial evidence" of efficacy as well as safety to obtain approval to market a new drug, and gave the Secretary of Health, Education, and Welfare the authority to suspend from approval a drug found to present an imminent hazard to the public health. The 1962 law was retroactive for "new drugs" first marketed under the 1938 law. After a two-year grace period, the Food and Drug Administration was directed to remove from the market those drugs that lacked evidence of effectiveness. Although the drug component of the Food, Drug and Cosmetic Act has not been significantly amended since 1962, controversies concerning the implementation and the effect of those amendments have abounded. A number of key issues have evolved from the controversy and led to the introduction of the currently pending legislation which, if enacted, would rewrite major sections of existing drug regulation law. It is clearly beyond the scope of this presentation to review all of these issues, but a few major ones can be cited.

First is the efficacy clause of the 1962 law. Proponents argue that it

represents the best in consumer protection, and opponents argue that it has led to a "drug lag," delay in the introduction of new drugs. An alternative approach recommended by the Dorsen Panel calls for replacing the current statutory standard of "safe and effective" with one requiring that the "benefits medically justify the risks." In determining whether a drug meets this standard one could take into account not only controlled studies of risk and effectiveness, but public health considerations and the availability of alternative drugs and modes of therapy.

Second is the issue of suspension of a drug from interstate commerce, namely, whether to replace the current "imminent hazard provision" with one less difficult to demonstrate such as "unreasonable and substantial risk of illness or injury." Other issues include postmarketing surveillance, accelerating approval of so-called "breakthrough drugs," that is, those that represent a major therapeutic advance, and patient package inserts. Patient package inserts are designed to inform consumers in clear language of the indications and proper use of drugs and any dangers or adverse consequences. Although patient package inserts are being developed for some drugs at this time, the Food and Drug Administration would like clear statutory authority to further this practice.

In 1976 the government's concern for the safety and efficacy of medical technology was directed toward medical devices, and the medical device amendments to the Food, Drug and Cosmetics Act were passed. This act expresses concern for the proliferation, increasing sophistication, and potential hazards of medical devices which became apparent during the 1960s—the legislation being initially introduced in 1970. This Act breaks some new ground in how government regulates medical technology, and classifies medical devices into three classes, with increasingly stringent requirements for approval from Class I through Class III. Class III is generally reserved for those devices which are to be used in supporting or sustaining human life, in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury. The statute *presumes* but does not require that all implantable devices be classified as Class III. It authorizes the Food and Drug Administration to ban unsafe or ineffective devices by administrative order, and to restrict the use of a device either to persons with specific training or experience or to those in specified facilities if, because of the device's potential for harmful effect or other considerations, its safety and effectiveness could not be reasonably assured. This is an interesting departure from previous practice and

may be considered an experiment that, if successful, could be applied to drugs in the future. How useful this approach will be remains to be determined. At this point it has yet to be applied. Whether this is due to lack of a logical application of this principle or to fear of reaction of the medical profession is problematic. This Act also reflected growing concern for public involvement in the decision-making process. It provides for this in two ways, by having public representation on advisory panels and by requiring the release of a summary of the detailed information upon which Food and Drug Administration decisions are made regarding the safety and effectiveness of devices.

The regulatory aspect of safety and efficacy of drugs and devices is embodied in Food and Drug Administration law developed over three-quarters of a century but there are other approaches to these issues as well. The National Institutes of Health, officially established in 1948, is primarily dedicated to basic and applied research in biomedical science and today accounts for approximately 40% of the nation's investment in biomedical research and development. The allocation of the research dollars has a significant impact on the rate of development of new technology. For example, the amount of money allocated to development of an artificial heart will have a direct impact on the time at which this technology enters the market place. The National Institutes of Health is currently reviewing methods of setting priorities, especially in applied areas. Until recently, the National Institutes of Health concerned itself primarily with the development of technology and spent limited funds on evaluation of efficacy. In 1975 it spent 100 million dollars (5% of their budget) on 755 clinical trials related to efficacy. Only 25 trials evaluated surgical procedures. In addition, during the past two years it has held a series of consensus development exercises in an effort to synthesize the current state of our knowledge concerning selected technologies. The Institute attempts to disseminate information from these consensus development exercises throughout the medical community.

Despite these efforts to look at safety and efficacy, Congress felt the need for a more organized and coordinated approach to the evaluation of medical technology and passed the Health Services Research, Health Statistics and Health Care Technology Act of 1978. An Office of Technology Assessment report on safety and efficacy estimated that only 20% of procedures have been adequately tested by randomized clinical trials. The report of the House Subcommittee on Health and the Environment

noted that "There is an emerging consensus ... that many technologies have been widely adopted into medical practice in the face of disturbingly scanty information about their health benefits, clinical risks, cost-effectiveness, and social side effects. In addition, the use of some technologies persists long after it becomes evident that these technologies are of marginal utility, outmoded, and even harmful." (House Report 95-1190, p. 29)

The Health Care Technology Act established a National Center for Health Care Technology and the National Council on Health Care Technology. The new National Center for Health Care Technology (NCHCT), with the aid of the National Council, has four primary responsibilities:

1) To undertake and support medical technology assessments that address issues of safety, effectiveness, cost-effectiveness, and social and ethical impacts

2) To support studies that analyze the factors that affect the use of medical technologies and methods of disseminating information about technologies

3) To encourage and support research demonstrations and evaluations regarding the safety and efficacy of selected technologies—new and old. When appropriate and practical, the Center is to develop and disseminate exemplary norms, standards, and criteria concerning the use of the health care technologies that it has studied.

4) To make recommendations to the Health Care Financing Administration regarding policies for federal reimbursement for the use of medical technologies

This last charge I shall return to shortly.

So far, I have described two major methods by which government attempts to manage medical technology: by controlling the marketing of drugs and devices, and by evaluating and disseminating data on safety and efficacy of marketed technologies. In addition to the problem of safety and efficacy, however, we face the problem of appropriateness of use. To address this problem, the government turned to the reimbursement system, and in 1972 established the Professional Standards Organization Program (PSRO).

The PSRO program was designed to assure that all health care services provided under federal programs are medically necessary, meet professional, recognized standards of care, and are provided at the most economical level possible consistent with quality care. The major activity of the

PSROs has been centered around monitoring hospital admissions and length of stay in an effort to control costs. The evaluation of the program has been similarly directed toward evaluating its impact on reducing hospital admissions and length of stay. To date, the full and potential impact of the PSRO program has not been assessed. During this past year the Health Care Financing Administration has begun to place more emphasis on the utilization of services, including ancillary services, rather than just length of stay. Identification of unnecessary or inappropriate use of technology is a major challenge. The introduction of a second opinion program for surgical procedures and attempts to educate the consumer concerning unnecessary roentgenograms and other invasive procedures have also been instituted. Further consideration of how the reimbursement system can be utilized to control use is being explored.

The Social Security Act mandates that the Medicare program shall pay only for services "reasonable and necessary" for diagnosis, treatment, or improved functioning. Medicare coverage decisions thus can affect the rate at which new technologies are utilized and inefficacious and unsafe ones are phased out. Generally, this has been interpreted to mean that once a procedure has moved from experimental status and is accepted by the local community it is "deemed reasonable and necessary." This decision is usually made locally, but when a coverage question is referred to the central Health Care Financing Administration office, they in turn request a recommendation from the Public Health Service. This service has traditionally applied four criteria to coverage recommendations: safety, efficacy, stage of development, and acceptance by the medical community. These recommendations have generally not attempted to specify indications for use; rather, that is left to the PSRO mechanism. The Health Care Financing Administration did, however, set a precedent in the case of the computerized tomography (CAT scan) decision by restricting coverage to uses supported by current evidence of efficacy. The Health Care Financing Administration and the Public Health service are considering several actions, including issuing more guidelines which relate coverage to appropriate indications for use and utilizing cost as a criteria. The National Center for Health Care Technology is considering utilizing three additional criteria in making their recommendations to the administration, namely, conformity to health planning guidelines, relative efficacy, and cost-effectiveness. The methodological problems faced in applying the last two criteria are large.

In trying to use these additional criteria, the agency is faced with the major problem of looking not at the technology under consideration in isolation from how it is used but is forced to address the issue of appropriate use. As an example, let us take a simple low cost, generally accepted procedure such as a skull roentgenogram. Many have questioned the use of skull films routinely in emergency rooms. If indeed skull films are clearly shown to be cost effective under certain conditions and not under others, will a definition be made as to under what conditions reimbursement will be made? Will PSROs be asked to oversee the implementation of such decisions? It has been suggested that procedure reimbursement protocols be developed to specify under what conditions of use a technology would be paid for. Under a fee-for-service, item by item, reimbursement system this would be the logical outcome of attempts to use relative efficacy and cost effectiveness in reimbursement decision making.

Further, the office of Technology Assessment has studied the methodology of cost effectiveness and its usefulness as a tool in resource allocation. Cost effectiveness analysis attempts to define all the costs of a technology and to weigh these against the effects. While the costs are presented in dollars, the effects are measured in improved health status or other defined outcomes. A number of methodological problems exist in attempting to carry out these studies, but suffice it to say that some of these problems can be expected to be overcome by further research while others—such as valuing intangibles—appear to be inherent in the analysis itself. The important issue, however, is not whether we can do cost-effectiveness analyses but rather, having done an analysis, how should it be used? First, it should be recognized that having found that "x" cost gives "y" effect does not tell us whether we should spend that amount to obtain the specific effect. Cost effectiveness analysis is receiving more favor in the health field than cost benefit analysis because many object to expressing health benefits in dollars. But if one tries to use cost effectiveness analysis to determine reimbursement policy we face a variant of the same dilemma, namely, how much we are willing to pay, for example, for an additional year of life. It is for these reasons that alternative reimbursement systems have been recommended, two of which are prospective budgeting and capital cost controls. Under both of these systems hospitals at least would know how much money would be available for the coming year and could, in cooperation with their medical staff, and hopefully the

community, make their own decisions as to what services should be provided. Cost effectiveness analyses could be used locally to make decisions as to which competing technology would receive priority or what limits would be placed on utilization of resources. It would at least have the advantage of placing the decision-making process in the hands of the users at the local level.

Although this approach would be appropriate for most technologies in daily use, it is unlikely to prove applicable to decisions regarding the development and introduction into general use of such technologies as an artificial heart and heart and other organ transplants. Decisions regarding the commitment of major resources will need to be made at the federal level by some mechanism that allows for a weighing of competing programs in an orderly manner.

The last major program that I shall mention is that established by the National Health Planning and Resources Development Act. Some of the provisions dealing with the development of state health plans and those provisions dealing with certificate of need are designed to regulate the diffusion of expensive medical equipment and the number and scope of health facilities, including services offered. The development of national guidelines for health planning is the responsibility of the federal government, while their implementation rests at the state and local levels. In developing the guidelines for major equipment use and the number and size of specialty services, two approaches have been used. One tries to determine the need for the service on a population base and to set standards on number per thousand population. The other approach determines optimum utilization and sets standards on number of procedures per year. Although most would agree that the population base is preferable, lack of adequate data has in some cases led to the use of utilization standards. Another important policy issue relates to the power of the guidelines. Although entitled "guidelines," a state whose plan is not in accordance with the guidelines can lose funds. Does this not indeed make the guidelines more like regulations than guidelines? How adaptable are the guidelines to local situations? These issues will continue to be debated by Health and Human Services and the National Council on Health Planning.

In summary, government management of medical technology dates back to the beginning of this century and impinges on all aspects, from development through evaluation, diffusion, and use. The National Insti-

tutes of Health is the primary agency in stimulating development. The Food and Drug Administration is the agency charged with protecting the public but frequently accused of hindering development. Both are involved in evaluation of safety and efficacy. Initial diffusion of drugs and devices is controlled by the latter, and general diffusion of at least expensive technologies is influenced by the Health Planning Law, specifically designed to address that issue. Information dissemination has been the primary responsibility of the former, but it is an area in which the Food and Drug Administration currently plays a more prominent role, while the National Center for Health Care Technology is now also charged with this responsibility.

Finally, the use of technology is the primary concern of PSROs, while Medicare reimbursement policy is being reexamined to determine how best these policies may be utilized, primarily in an effort to control costs. Our approach to the evaluation and use of medical technology has been influenced by two major goals. Initially, our concern was to assure that all safe and effective technology was equally available to all citizens. More recently the goal has been to assure that this is accomplished at reasonable cost. However, we have yet to define reasonable cost, thus leaving us with the dilemma of how best to balance the benefits and costs of medical technology.